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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/838,382	04/20/2001	Harry D. Danforth	0100.00	9258

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EXAMINER	
HINES, JANA A	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 06/18/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/838,382	DANFORTH ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *3-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 March 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Amendment Entry

1. The amendment filed March 31, 2003 has been entered. The examiner acknowledges the amendment to the specification.

Election/Restrictions

2. Applicant arguments about the restriction are essentially that the inventions recited in claims 3-11 should be included with the immunovariant strain of group I. Applicants assert that there is no serious burden on the Examiner to search and that the applicants believe that groups II and III should be grouped together.

However it is the examiner's position that the inventions in I and II and III are related as different products. As previously stated the products are distinct as claimed because they have different structures and different uses. Each group has a different effect and is capable of use without the other. For instance, the *E. maxima* strain product of Group I can be used in a method to detect *E. maxima* infection however the vaccine products of Group II and III could not be used in a method of detection; since they have different uses and functions. While Groups II and III are drawn to vaccines, Group III requires the use of oocysts from an immunovariant strain which must have characteristics that correspond to the strain *E. maxima*-I, whereas the strain claimed in Group II does not; thus the groups comprise different components with different characteristics, thereby resulting in different effects and being capable of separate uses. Each group has a different structure, requires different components, produces different

effects and is capable of different functions as compared to the other groups. Therefore, the products of the inventions are distinct as claimed.

Applicants argue that there would be no serious burden on the Examiner to search the other groups. Where the related inventions as claimed are shown to be distinct under the criteria of MPEP § 806.05(c) - § 806.05(i), the examiner has shown separate classification thereof : This shows that each distinct subject has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Examiner has met the requirements to show distinctness and as such has set forth that searching for the strain does not require, for example, that protective immunity of a vaccine be determined; the challenge data to be analyzed; determination of which class of patients the vaccine can be administered to, at what doses or what the mode of administration is. Therefore, a serious burden would be placed on the examiner to search all of the claims. Therefore applicants' argument that claims 3-11 should be grouped with claims 1-2 is not persuasive. And the requirement is still deemed proper and is therefore made FINAL.

3. Therefore claims 1-2 are under consideration in this office action, while claims 3-13 are withdrawn from consideration.

Drawings

4. The corrected or substitute drawings were received on March 31, 2003. These drawings are acceptable.

Sp cification

5. The specification at page 11 lines 27-28 still fails to recite the deposit information with respect to the Accession number. Appropriate correction is required.

The use of the trademark COCCIVAC™ and other commercial vaccines has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Response to Arguments

6. Applicant's arguments filed March 31, 2003 have been fully considered but they are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. The deposit rejection of claims 1-2 under 35 U.S.C. 112, first paragraph, is maintained. The rejection was on the grounds that the specification lacks complete deposit information for the deposit of the strain designated *E. maxima*-I. Because it is not clear that cell lines possessing the properties of *E. maxima*-I are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the claims require the *E. maxima*-I strain, a suitable deposit for patent purposes is required. Without a publicly available deposit of the above cell line, one of

ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the cell line is an unpredictable event.

Applicants assert that a statement about depositing the strain is sufficient to overcome the rejection; it is examiner's position that applicants' statement without an accession number is not sufficient. A viability statement for deposit of biological material must contain the identity of the deposit and the accession number given by the depository. Since the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the *E. maxima*-I strain described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed. Applicant's attention is directed to In re Lundack, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR §1.801-1.809 for further information concerning deposit practice.

Applicants' attention is pointed to M.P.E.P §2406.02 entitled Deposit After Filing Date –Corroboration. When the original deposit is made after the effective filing date of an application for patent, an applicant is required to promptly submit a statement from a person in a position to corroborate that the biological material which is deposited is a biological material specifically identified in the application (the filing date of which is relied upon) as filed. The nature of this corroboration will depend on the circumstances in the particular application under consideration, including the length of time between

the application filing date and the date of deposit. While few, if any, situations can be imagined where the description requirement of 35 U.S.C. 112 can be satisfied where the biological material was not in existence at the time of filing, the rules will not preclude such a situation as there is no requirement in the patent law that an actual reduction to practice occur as a condition precedent to filing a patent application.

Applicants' attention is also pointed to M.P.E.P §2406.03 entitled Possible Loss of U.S. Filing Date in Other Countries. Those applicants intending to file patent applications in a country foreign to the United States relying upon biological material that must be deposited to satisfy the requirements of 35 U.S.C. 112 when the application is filed in the United States are cautioned that in many countries the deposit must be made before the filing date of the priority application in order to obtain foreign priority rights. Thus, while the deposit of a biological material subsequent to the effective filing date of a United States application is sufficient to comply with 35 U.S.C. 112, an applicant may not be able to rely on the filing date of such a U.S. application if a patent is sought in certain countries foreign to the United States.

Therefore the rejection will not be withdrawn until complete deposit information is disclosed.

8. The rejection of claims 1-2 under 35 U.S.C. 112, second paragraph is maintained. The rejection was on the grounds that the term "immunovariant" in claims 1-2 is a relative term that renders the claim indefinite.

Applicants argue that the term is used and well known in the art and evidences such by showing its use on the Internet. However it is the examiner's position that the term "immunovariant" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the invention. The use of the term fails to teach how much variation is allowed for a strain to be considered an immunovariant. Applicants have failed to point to support in the specification. Applicants broad definition that proteins, cell lines, and strains of bacteria, viruses and parasites can be immunovariants fails to specifically describe what strains of E. maxima will or will not be characterized as immunovariant strains. Therefore, the rejection is maintained and applicants' arguments are not persuasive.

9. The phrase "corresponds in characteristics to the strain *E. maxima*-I" in claim 2 is a relative term that renders the claim indefinite. Applicants have provided that definition of characteristics is found in the dictionary; however the generic definition fails to define the corresponding characteristics to the strain *E. maxima*-I. The generic definition fails to provide a standard for ascertaining which corresponding characteristics of the *E. maxima*-I strain applicant is referring. Applicant has failed to claim any corresponding characteristics. The claims fail to recite how much correspondence is needed for a strain to correspond. Therefore, the rejection is maintained and applicants' arguments are not persuasive.

10. The rejection of claims 1-2 under 35 U.S.C. 102(b) as being anticipated by Barta et al., is maintained for reasons already of record. The rejection was on the grounds that Barta et al., teach obtaining the *E. maxima* Guelph and Maryland strains and that such strains are immunovariant strains of the strain designated as *E. maxima*-I.

Applicants state that the claims are drawn to a specific strain deposited at ATCC, however the claims do not recite an ATCC accession number; applicants' claims are not limited as argued. Applicants' claims are interpreted as being significantly broader, and thereby incorporate any antigenic variation of *E. maxima*.

Applicants argue that the strains of Barta et al., are not the same as the strain designated as *E. maxima*-I, however, the claims lack any defining characteristics. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies i.e., protection against challenges with *E. maxima*-I are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore applicants' arguments are not persuasive since the claims fail to recite specific functional or structural features. Since applicants have failed to claim the deposited strain, the strains of Barta et al., meet the broad requirements of the claim. It is noted that the claims fail to recite which characteristics of *E. maxima-I* must correspond, therefore the any common characteristics of strains, such as the ability to provide protection will be viewed as meeting the requirements of the claim. The Barta et al., strains provides protection after the challenge experiments;

therefore according to applicants broad definitions, the requirement that the strains share corresponding characteristics of the claims are met. Accordingly the rejection is maintained.

11. The rejection of claims 1-2 under 35 U.S.C. 102(b) as being anticipated by Martin et al., is maintained for reasons already of record. The rejection was on the grounds that Martin et al., teach an immunovariant strain of *Eimeria maxima*, and an immunovariant strain of *Eimeria maxima* that corresponds in characteristics to the strain *E. maxima*-I as claimed.

Again, applicants state that the claims are drawn to a specific strain deposited at ATCC, however the claims do not recite an ATCC accession number; and applicants' claims are not limited as argued. Applicants' claims are interpreted as being significantly broader based on the broad claim language and lack of claiming a deposited strain or a strain with any functional or structural characteristics.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies i.e., protection against challenges with E. maxima-I are not recited in the rejected claims. Applicants argue that the strains of Martin et al., are not the same as the strain designated as *E. maxima*-I, however, the claims lack any defining characteristics. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore, applicants assertions about the unclaimed

protection ability of the strain designated as *E. maxima-I* is not persuasive since the claims fail to claim said characteristics. Applicants' have failed to claim the deposited strain, the strains of Martin et al., meet the broad requirements of the claim. It is noted that the claims fail to recite which characteristics of *E. maxima-I* must correspond, therefore any common characteristics of strains, such as the ability to provide protection will be viewed as meeting the requirements of the claim. The Martin et al., strains provide protection after the challenge experiments; therefore according to applicants broad definitions, the requirement that the strains share corresponding characteristics of the claims are met. Accordingly the rejection is maintained.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines
June 11, 2003

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